2014 National Institutes of Health Clinical Center
Strategic and Annual Operating Plan

Warren G. Magnuson Clinical Center
Mark O. Hatfield Clinical Research Center

Message from the Clinical Center Director

We enter 2014 amid both exciting and challenging times. The strides made in treating and curing diseases during the NIH Clinical Center's first 60 years have saved, lengthened and improved countless lives, and brought us to the threshold of even more exciting discoveries. Yet, we are ever mindful of the limitations imposed by a tough fiscal climate. Through efficient and careful planning, we prioritize and maximize resources dedicated to clinical research and patient care. Collaboration and new partnerships are key. For the first time ever, we look forward to providing extramural researchers from both academia and industry with access to the Clinical Center. Outside scientists who became the first recipients of a new collaborative grant program in late 2013, will bring exciting new ideas to the intramural program. They will leverage the unique attributes of the Clinical Center to test promising laboratory discoveries using emerging technologies and tools, a range of biomedical specimens including those for rare diseases, and other research resources.

Another important development for 2014 involves our insurance billing pilot. The pilot was prompted by a Congressional Appropriations Committee report. Following intense preparation in 2013, we will formally launch a pilot this year to explore the feasibility of insurance billing, including assessing the impacts on clinical research and patient care. This endeavor is a significant one and our aim is to initiate a credible pilot while limiting disruption to our patients and clinicians.

Our 2014 Operating Plan also shows that several ongoing activities continue to gain momentum. We remain tireless in delivering innovative training programs in clinical research, designing and implementing new strategies that support the NIH's research vision, and developing measures for success in clinical research. We are also steadfast in strengthening our culture of patient safety, in order to provide our investigators and research participants with the best environment for clinical research.

By its nature, our mission remains a work in progress. We believe this plan enables us to continue to build on our rich legacy of meaningful accomplishments. Behind the strength of collaboration, wise planning, responsible stewardship of resources, and a diverse world-class staff with unending dedication to mission, we look forward to yet another year of turning discovery into better health.

John I. Gallin, M.D.
Director, NIH Clinical Center

Planning Framework
[Graphic: Planning Framework]

This is a circular graphic that depicts the Clinical Center planning framework which represents a continuous improvement model. The outside circle encompasses in Environmental Influences including

Internal & External Stakeholder Input, Key Influencing Factors, and Governance & Advisory Groups depicted as a continuous loop.

The interior circle reflects the strategic components of the plan including Vision & Mission, Guiding Principles, and Long Term Goals. The vision and mission feed into the core processes which then inform the long term goals.

The middle circle represents the operational components of the plan and has at the heart the annual targets. The annual targets are encircled with a plan-do-check-act cycle.

Planning/Budget Review Process

[Chart: Planning/Budget Review Process]

October/November
• Institute Planning Meetings (this is a programmatic requirement)

December
• CC Identifies Priorities and Develops Plans (this is a programmatic requirement)

January/February
• CC Prepares Budget (this is a programmatic requirement)

February/March
• NIH Advisory Board for Clinical Research (Reviews)

April/May
• NIH Clinical Center Governing Board (Reviews)

May/June
• NIH Steering Committee (Reviews)

July
• IC Directors (Reviews)

September
• NIH Director (Reviews)

Vision Statement

A vision statement answers the question: "What do we strive to be?" and is a shared view that defines what the organization wants to do or become.

> As America's research hospital, we will lead the global effort in training today's investigators and discovering tomorrow's cures.

Mission Statement

A mission statement answers the question: "What is our fundamental purpose?"

The NIH Clinical Center provides a model environment for:
- clinical research
- patient care
- training

Guiding Principles

Guiding principles are the values underpinning the activities undertaken by an organization.

Respect for the Individual
At the heart of the NIH Clinical Center mission is a deep and abiding respect for the rights, preferences, and values of the individuals and communities we serve.

Innovation
The NIH Clinical Center encourages and promotes innovative practices in clinical research, patient care, training, and operations.

Diversity and Inclusion
By bringing diverse individuals together, the NIH Clinical Center addresses the issues facing the global community of patients and staff while promoting an inclusive environment.

Dissemination of Information
The NIH Clinical Center fosters global communication to disseminate innovations.

Judicious Use of Resources
Through efficient practices, the NIH Clinical Center maximizes resources dedicated to clinical research and patient care.

Long Term Goals: 2014-2018

Long range goals translate the vision, mission and guiding principles into performance-based action plans intended for the next five years.

Clinical Research
Realize the NIH clinical research vision for pediatrics, genomics, the brain initiative, and translational therapeutics, including biologic interventions, biomarkers, and diagnostics.

Patient Care
Strengthen the culture of patient safety by minimizing adverse events, engaging patients, and leveraging health information technology.

Training
Use emerging technology to deliver innovative training programs in clinical research, patient safety, and service excellence.

Annual Targets

[Chart: Annual Targets]

Annual targets are key initiatives identified to support the long range goals. Each target is assigned to a member of the executive team who is held accountable for leadership, strategy development, and results.

Mission Element: Clinical Research
Long Range Goals: Realize the NIH clinical research vision for pediatrics, genomics, the brain initiative, and translational therapeutics, including biologic interventions, biomarkers, and diagnostics.
2014 Annual Targets:
- Implement first cycle of grants - *"Opportunities for Collaborative Research at the NIH Clinical Center"*
- Partner with NHGRI to expand whole exome sequencing
- Facilitate development of scope and vision for pediatrics at the NIH intramural research program
- Design and build new cell therapy infrastructure

Mission Element: Patient Care
Long Range Goals: Strengthen the culture of patient safety by minimizing adverse events, engaging patients, and leveraging health information technology.
2014 Annual Targets:
- Implement electronic surveillance of patient records to identify risks and adverse events
- Launch quality improvement projects related to Culture of Patient Safety Survey
- Capture patient feedback at point of care
- Deploy mobile technologies for clinical information management

Mission Element: Training
Long Range Goals: Use emerging technology to deliver innovative training programs in clinical research, patient safety, and service excellence.
2014 Annual Targets:
- Launch new training module to improve patient safety and clinical quality
- Host new program for underrepresented minorities on careers in clinical research and health care
- Provide new training in FDA IND regulatory requirements
- Develop and implement a pipeline for training Native American nurse scientists and clinicians

Overarching Element: Implement insurance billing pilot for patient services

Financial Assessment of Annual Targets
[Chart: Financial Assessment of Annual Targets]

Overarching Initiative
Annual Target: Implement insurance billing pilot for patient services
Financial Impact for 2014: $5.9M to-date funded centrally by NIH

Clinical Research
Annual Target 1: Implement first cycle of grants - *"Opportunities for Collaborative Research at the NIH Clinical Center"*
Financial Impact for 2014: Funding from Institute-supported grants

Annual Target 2: Partner with NHGRI to expand whole exome sequencing
Financial Impact for 2014: No Clinical Center funds required; staff support provided from existing Clinical Center resources

Annual Target 3: Facilitate development of scope and vision for pediatrics at the NIH intramural research program
Financial Impact for 2014: No operating funds will be expended in planning phase

Annual Target 4: Design and build new cell therapy infrastructure
Financial Impact for 2014: Facility funded by NIH; $0.5M activation requested by Clinical Center for FY15

Patient Care
Annual Target 1: Implement electronic surveillance of patient records to identify risks and adverse events
Financial Impact for 2014: 0.5 RN FTE to monitor EHR, track trends, and initiate follow up

Annual Target 2: Launch quality improvement projects related to Culture of Patient Safety Survey
Financial Impact for 2014: Existing resources; CC department quality improvement (QI) resources will fund cross-functional teams

Annual Target 3: Capture patient feedback at point of care
Financial Impact for 2014: 0.25 FTE to design, develop, and monitor; technology costs dependent upon project design

Annual Target 4: Deploy mobile technologies for clinical information management
Financial Impact for 2014: Internal resources deployed for planning and development

Training
Annual Target 1: Launch new training module to improve patient safety and clinical quality
Financial Impact for 2014: Training module purchased with FY13 funds; $15K annual expense

Annual Target 2: Host new program for underrepresented minorities on careers in clinical research and health care
Financial Impact for 2014: Not anticipated to require operating funds

Annual Target 3: Provide new training in FDA IND regulatory requirements
Financial Impact for 2014: Existing resources

Annual Target 4: Develop and implement a pipeline for training Native American nurse scientists and clinicians
Financial Impact for 2014: Salary and benefits for post-doc fellow from existing Nursing research budget; requesting additional funds from NIH partners over a 3 year period

Other Ongoing and New Activities
[Chart: Ongoing and New Activities]

In addition to the Annual Targets, the Clinical Center has plans to pursue a number of important ongoing and new activities not included in this plan. All activities, whether or not included as priorities in this plan, are evaluated regularly and adjustments are made to the Clinical Center's portfolio of activities to ensure that adequate resources are allocated to continue important baseline activities as well as Annual Targets.

Clinical Research Support

Activity Outside of this Plan: Research participant perception surveys (Ongoing)
Comments: Collaborating with Clinical Translational Science Awards (CTSA) network to assess the perceptions of clinical research participants about their experiences

Activity Outside of this Plan: Inducible pluripotent stem cell (iPSC) and embryonal stem cell initiative (Ongoing)
Comments: Creation of a facility to support clinical translation of science using these techniques

Activity Outside of this Plan: Traumatic Brain Injury/Post Traumatic Stress Disorder collaboration (Ongoing)
Comments: Providing clinical assistance and clinical research support for this joint initiative with Walter Reed National Military Medical Center

Activity Outside of this Plan: Translation Research In Pediatrics Program (TRIPP) (Ongoing)
Comments: Developing with Children's
National Medical Center

Activity Outside of this Plan: NIH/FDA Center for Drug Evaluation and Research (CDER) collaboration (Ongoing)
Comments: Training and ready access to FDA for clinical investigators

Activity Outside of this Plan: Refine clinical research metrics of success (Ongoing)
Comments: Focus will be on outcome metrics, possibly including new drugs, devices, publications, etc.

Activity Outside of this Plan: Tool for prospective protocol resource planning (Ongoing)
Comments: Has applicability for insurance billing and U01 collaboration grants as well

Patient Safety/Clinical Care

Activity Outside of this Plan: Clinical Research Nursing-setting the leadership agenda (Ongoing)
Comments: The Nursing Department is expanding its work on advancing clinical research as a nursing subspecialty to include development of core metrics and defining the role of leadership in a clinical research environment

Activity Outside of this Plan: Management of the hospital environment to prevent outbreaks of multiply-resistant organisms (Ongoing)
Comments: The Clinical Center is continuing to monitor existing and new organisms

Activity Outside of this Plan: Clinical Dashboards (Ongoing)
Comments: Consolidate and automate collection and analysis of clinical quality and patient safety performance data

Activity Outside of this Plan: Implement a framework for assessing performance of clinical research units (New)
Comments: Conduct detailed unit level assessment of each patient care unit.

Training

Activity Outside of this Plan: Core Clinical Research Curriculum (Ongoing)
Comments: Principles and Practice of Clinical Research course – Brazil, September 2014

Activity Outside of this Plan: Medical Research Scholars Program (MRSP) (Ongoing)
Comments: Pursuing sustained public and private funding for program

Activity Outside of this Plan: Assessment of Training Program Alumni Productivity (New)
Comments: Determining metrics of success and program output for alumni of NIH one-year training programs (CRTP, MRSP)

Information Technology

Activity Outside of this Plan: Clinical Research Information Systems (Sunrise Clinical Manager/SCM) upgrade (New)
Comments: Required upgrade of the system to version 6.0

Activity Outside of this Plan: Transition to transparent acuity classification (Ongoing)
Comments: System driven from clinical documentation

Activity Outside of this Plan: Rollout Two-Factor Authentication to Nursing Inpatient Units and Outpatient Clinics, and areas with shared workstations including Radiology and Laboratory Medicine and Perioperative Medicine (Ongoing)
Comments: Mandated Workstation on Wheels (WOW), Shared Computer, Apple Two-Factor implementation: June 2014

Activity Outside of this Plan: Develop protocol order set Service Center (Ongoing)
Comments: Establishes process to drive use of protocol order sets in CRIS

Activity Outside of this Plan: Medication bar-coding implementation (Ongoing)
Comments: Complete the final component of the Clinical Center enterprise bar-coding initiative

Capital Equipment/Facilities

Activity Outside of this Plan: Major renovation of Clinical Center departments located in Ambulatory Care Research Facility (ACRF) (Ongoing)
Comments: Includes imaging, OR's, transfusion medicine, laboratory medicine, and PET. Funding requested from NIH Building & Facilities budget

Activity Outside of this Plan: Renovation of admissions area to provide private consenting space while separating admissions and patient business functions (Ongoing)
Comments: Business functions (Cashier and Voucher) will move to newly renovated space in late Winter and Admissions renovations will be complete in Spring 2014

Workforce

Activity Outside of this Plan: Clinical Center Employee Survey (New)
Comments: Assess employee satisfaction in areas such as career development, management, work environment, employee engagement, and diversity

Activity Outside of this Plan: Comprehensive Workforce Data Reviews by Clinical Center Departments (Ongoing)
Comments: Conduct department-level workforce analysis and planning based on compensation and award history, turnover, retirement eligibility, diversity, and employee survey data including onboarding and separation surveys

Activity Outside of this Plan: Project SEARCH (Ongoing)
Comments: Expand training and hiring for individuals with intellectual disabilities

Measuring Success
[Graphic: Operational Metrics]
The Balanced Scorecard[1] approach below illustrates the operational metrics used by the Clinical Center to evaluate performance which are monitored and reported throughout the year.

Operational Metrics

> **Operational Management**
> • Cost Per Adjusted Patient Day
> • CC Department Metrics
>
> **Clinical Research**
> • Clinical Activity
>   ▪ Active Protocols

- Protocols by Type
- Training
  - Clinical Research Curriculum Participants
- Bench-to-Bedside Program
  - Applications and Awards
- U01 Collaborations Program
  - Applications and Awards

Workforce
- Staffing
  - FTE Utilization
  - Turnover
  - Recruitment/Departures
- Accountability/Performance Management
  - Awards
  - Compensation
- Leadership Development
  - Curriculum Participation
  - Competency/Mandatory Training Compliance
- Diversity
  - Underrepresented Minorities

Patient Care and Safety
- Patient Activity
  - Inpatient Days
  - Outpatient Visits
- Clinical Quality
  - Wait Times
  - Patient Falls
  - Hand Hygiene
  - Medication Errors
- Patient Perception
- Ongoing Surveys

[1] Developed in accordance with the Kaplan and Norton Balanced Scorecard Method.
www.balancedscorecard.org/ accessed January 15, 2014.